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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,256	03/11/2004	Zichria Zakay-Rones	85189-5900	1732

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,256	ZAKAY-RONES ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36 and 38-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36, 38-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *8/4/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other Notice to Comply

DETAILED ACTION

Claims 1-36 and 38-55 are pending.

The amendment to claims 10, 17, 31, 34-36, 47 and 49, and the cancellation of claim 37 filed on 12/10/04 is acknowledged by the examiner.

The disclosure is objected to because of the following informalities: This application contains sequence disclosures that are encompassed by the definition for nucleotide sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with requirements of 37 CFR 1.821 through 1.825 because there are sequences listed in the specification on pages 15-17 and 20-21, but the SEQ ID NOs for the sequences are not listed in the specification. The amino acid in Figure 10 is missing a SEQ ID NO and is not listed in the CRF.

A complete reply to the election/restriction requires compliance with requirements of 37 CFR 1.821 through 1.825 or the response will be considered non-responsive.

In view of the interview summary and because of the term "the at least one isolated polynucleotide" being recited in claim 46 and not claim 45, claims 47-52 will be considered to be dependent on claim 46 and not claim 45. Claims 47-52 will be grouped with the group that contains claim 46.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 24-30, 46-52, and 55, drawn to a clonal lentogenic oncolytic strain of Newcastle Disease Virus (NDV) comprising the DNA nucleotide sequence of

SEQ ID NO: 1 and an in vivo method for treating cancer in a patient using a lentogenic oncolytic strain of NDV, classifiable in class 424, subclass 93.2.

II. Claims 6-14, and 31-45, drawn to a pharmaceutical composition comprising a lentogenic oncolytic strain of NDV and at least one viral glycoprotein from NDV and method of using the composition for treating cancer in a patient, classifiable in class 514, subclass 2 and class 424, subclass 93.2.

III. Claims 15-23 and 55, drawn to a composition comprising at least one viral glycoprotein and a suitable carrier, classifiable in class 530, subclass 350.

IV. Claims 53 and 54, drawn to an ex vivo method for treating cancer in a patient using a host cell transfected with an isolated polynucleotide encoding at least on viral polypeptide, an analog, or subunit having oncolytic activity or a vector comprising the isolated polynucleotide, classifiable in class 424, subclass 93.21.

NOTE: Claim 55 contains an improper Markush Group because the claims recite using an isolated glycoprotein or a subunit or analog thereof or an isolated polynucleotide encoding an isolated glycoprotein or a subunit or analog thereof. As set forth in *In re Harnisch* (631F.2d 716 206 USPQ 300 (CCPA 1980), see MPEP 803.02, unity of invention exists for all species in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. DNA is used to express a protein, whereas a protein does not require the DNA for expression. A polypeptide and a nucleic acid do not share a substantial structural feature. Thus, the polypeptide and the nucleic acid will be separated into distinct groups.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of group III and the polynucleotide of group I are patentably distinct for the following reason: Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, while a polypeptide of group III can be made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptides can be isolated using affinity chromatography.

For these reasons, the inventions of group I and III are patentably distinct.

Furthermore, searching the inventions of group I and III together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Group I and III have a separate search status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searches in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest may by journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetic papers, which has no knowledge of the polypeptide, but spoke of the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search inventions group I and group III together.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the ex vivo method in group IV does not require the composition comprising the nucleic and the polypeptide in group II. Furthermore, searching the inventions of group II and IV together would impose a serious search burden. In the instant case, the search of the ex vivo method and the method using the composition comprising the polypeptide and the nucleic acid are not coextensive. The inventions of Group II and IV have a separate search status in the art as shown by their different classifications. As such, it would be burdensome to search inventions group II and IV together.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the ex vivo method in group IV does not require the composition comprising the polypeptide in group III. Furthermore, searching the inventions of group III and IV together would impose a serious search burden. In the instant case, the search of the ex vivo method and the composition comprising the polypeptide are not coextensive. The inventions of Group III and IV have a separate search status in the art as shown by their different classifications. As such, it would be burdensome to search inventions group III and IV together.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does

not disclose that these methods and/or product would be used together. The in vivo method of delivering a nucleic acid (group I) and the ex vivo method of delivering a nucleic acid (group IV) are unrelated as they comprise distinct steps or material and utilize different products which demonstrates that each method or product has a different mode of operation, different effect, or different function. Group I is directed to in vivo nucleic acid delivery and Group IV is directed to ex vivo nucleic acid delivery. Moreover, the methodology and materials necessary for delivering a nucleic acid differ significantly for each of the materials or methods. Therefore, each method is divergent in materials and steps. For these reasons the inventions I and IV are patentably distinct. Furthermore, the distinct steps require separate and distinct searches. The Invention of Groups I and IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I and IV together.

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as delivering NDV to an individual to treat cancer in the individual. See MPEP § 806.05(d). Moreover, the methodology and materials necessary for delivering both products as required in group II compared to delivering one product in Group I differ significantly for each of the materials or methods. Therefore, each method is divergent in materials and steps. For these reasons the inventions I and II are patentably distinct. Furthermore, the distinct steps require separate and distinct searches. The Invention of Groups I and II have a separate status in the art as shown by

their different classifications. As such, it would be burdensome to search the inventions of Groups I and II together.

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III has separate utility such as polypeptide method of treating cancer in an individual. See MPEP § 806.05(d). Moreover, the methodology and materials necessary for delivering both products as required in group II compared to delivering one product in Group III differ significantly for each of the materials or methods. Therefore, each method is divergent in materials and steps. For these reasons the inventions II and III are patentably distinct. Furthermore, the distinct steps require separate and distinct searches. The Invention of Groups II and III have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups II and III together.

Because these inventions are distinct for the reasons given above and the search required for each Group listed above is not required for any other Group listed above and the search for each group is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

Brian Whiteman

Notice to Comply	Application No. 10/800,256	Applicant(s) ZAKAY-RONES et al.
	Examiner B. Whiteman	Art Unit 1635

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Figure 10 contains an amino acid sequence that is not listed in the CRF and pages 15-17 and 20-21 contain sequences that are missing SEQ ID NOs.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
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